

Update on Veronate

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APPENDIX 2



Veronate®

- Plasma-derived, donor-selected polyclonal IVIG
- High levels of IgG directed against staphylococcal proteins (MSCRAMM®)
 - *S. aureus* - ClfA
 - *S. epidermidis* - SdrG
- Formulated for premature infants
 - 0.2% NaCl
 - No sucrose
 - No preservative

Veronate® – Target Indication

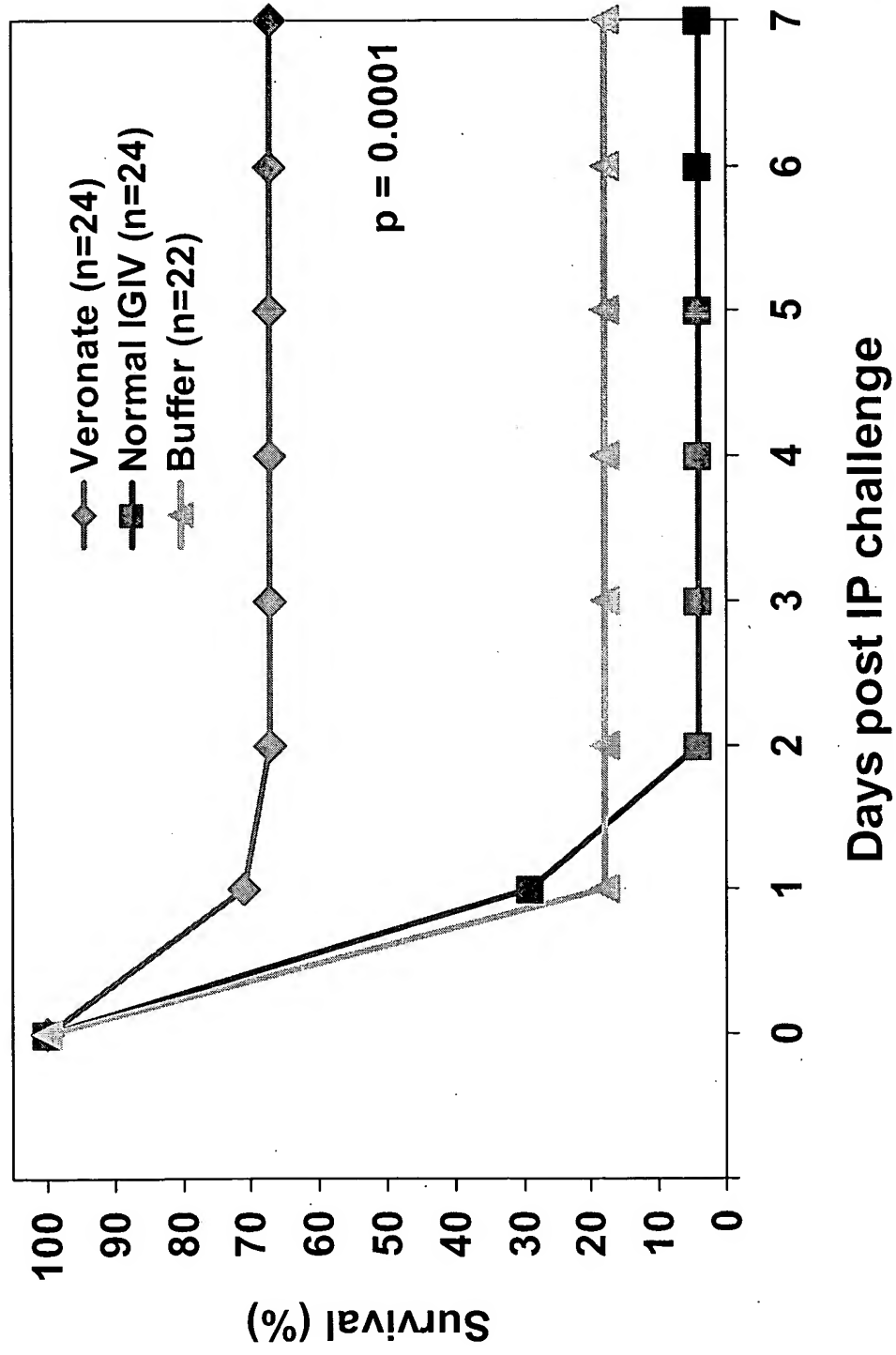
- Premature infants, 500 to 1250 grams
- Prevention of nosocomial infections due to:
 - *S. aureus*
 - *S. epidermidis*
- Other potential benefits
 - Reduction in candidemia
 - Reduce overall mortality



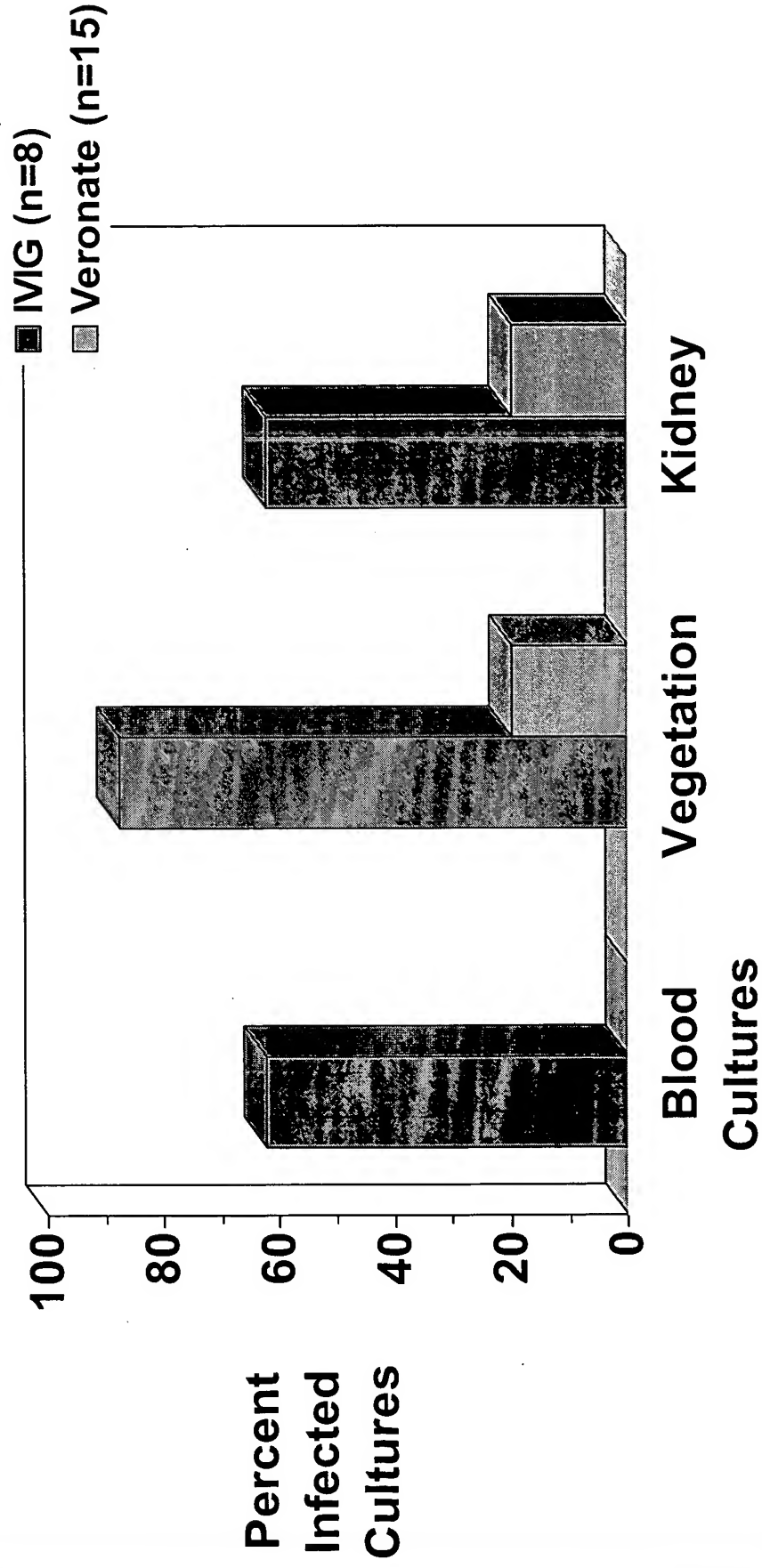
Pre-Clinical Studies

- Reduced mortality from *S. epidermidis* infection in 3-6 day old rats
- Reduced *S. aureus* and *S. epidermidis* bacteremia and tissue invasion in **prophylaxis** rabbit endocarditis model
- Reduced tissue invasion by both *S. aureus* and *S. epidermidis* in **treatment** of endocarditis in rabbit model

Veronate Prevents *S. epidermidis* Mediated Mortality in a Suckling Rat Model



Veronate Reduces the Incidence of *S. epidermidis* Infection in a Rabbit Model of Infectious Endocarditis



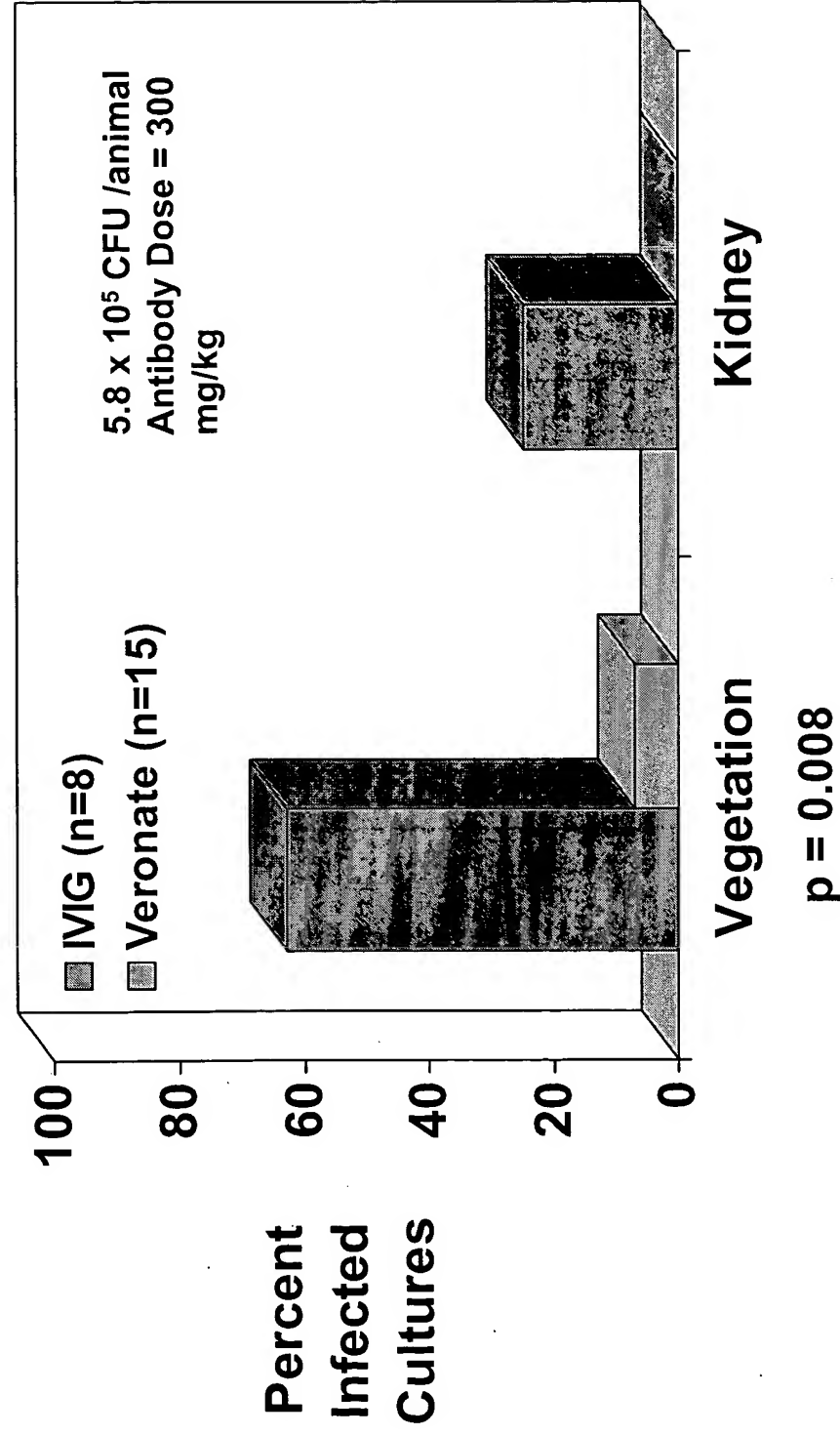
$p < 0.04$

$p < 0.03$

$p < 0.05$



Veronate Reduces the Incidence of *S. aureus* Infection in a Rabbit Model of Infectious Endocarditis



Summary of Phase II Results

- Veronate was well tolerated
 - 1,280 doses administered
- No significant difference in AE's or SAE's between placebo and treatment groups
- 750 mg/kg dose selected for pivotal Phase III trial
- Relative reductions between placebo and 750 mg/kg treatment cohorts on an intent-to-treat basis:
 - *S. aureus* infections – 63%
 - Fungal infections – 67%
 - All-cause mortality – 36%

Summary of the Trends in Phase II

- Magnitude of the observed differences in infection rates ~60%
- Differences observed at the highest dose tested
- Dose-response by time-to-onset analysis
- Differences for the Veronate targeted organisms
- Lack of effect on non-targeted organisms
 - Biologically plausible link to *Candida* spp